IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	§
Bryan et al.	§
	§
Patent No. 6,156,067	§
	§
Issued: December 5, 2000	§
	§
For: HUMAN DISC PROSHTHESIS	§
	§

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 35 U.S.C. § 156, and in compliance with 37 C.F.R. 1.710 et seq., Medtronic Sofamor Danek, Inc. ("MSD"), a corporation of the state of Indiana, with a principal place of business located at 2600 Sofamor Danek Drive, Memphis, TN 38312, and the owner of the above-identified patent, by its undersigned agent hereby makes application for an extension of the patent tem of its U.S. Patent No. 6,156,067, from November 14, 2014 to November 15, 2019.

(1) The approved product that is the subject of this application is a medical device subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA") and is indicated for motion-preserving procedures in treating degenerative disc disease of the cervical spine, comprising the following unit: the BRYAN® cervical disc (hereinafter the "Device").

(2) The regulatory review of the approved product was conducted by the Center for Devices and Radiological Health ("CDRH") of the Food and Drug Administration ("FDA") under Sections 515 and 520 of the FDCA.

(3) By letter dated May 12, 2009, the Office of Device Evaluation of the CDRH granted permission to begin commercial marketing of the approved product.

(4) This Application is being submitted within the sixty-day period permitted for submission of extension of patent terms pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), the last day of said sixty-day period being July 4, 2009. Because July 4, 2009, falls on a Saturday, the last day upon which this Application could be timely submitted is July 6, 2009.

(5) United States Patent No. 6,156,067, entitled "Human Disc Prosthesis," having inventors Dr. Vincent Bryan and Alex Kunzler, is the patent for which a term extension is being sought. United States Patent No. 6,156,067 issued on December 5, 2000, from Application Serial No. 08/856,846 filed on May 15, 1997 as a continuation-in-part application of application No. 08/681,230, now U.S. Patent No. 5,674,296, which is a continuation-in-part application of application No. 08/339,490, filed November 14, 1994, now abandoned. During prosecution of Application Serial No. 08/856,846, the term of U. S. Patent No. 6,156,067 that exceeded the term of commonly-owned U.S. Patent No. 5,674,296, was disclaimed. Thus, the term of U. S. Patent No. 6,156,067 is the same as that of U.S. Patent No. 5,674,296. As U.S. Patent No. 5,674,296 was filed before June 8, 1995, pursuant to 35 U.S.C. §154(c), the expiration date of U. S. Patent Nos. 5,674,296 and 6,156,067 is the longer of twenty years from the filing date of the earliest application from which U. S. Patent No. 5,674,296 claims priority, or seventeen years from the date of issuance, or November 14, 2014.

(6) A copy of U. S. Patent No. 6,156,067, including the entire specification, claims and drawings, is appended hereto as Exhibit A.

(7) Copies of the 3½ and 7½ year maintenance fee payments also are appended hereto, forming Exhibit B. Copies of a first terminal disclaimer, as well as a "corrected" second disclaimer, are appended hereto, forming Exhibit C. There are no certificates of correction, nor any re-examination certificates that have issued to date with respect to U.S. Patent No. 6,156,067.

(8) United States Patent No. 6,156,067 claims the approved product identified in paragraph (1) above, and the following is a showing which lists each applicable claim of said Patent and demonstrates the manner in which at least one such patent claim of said Patent reads on the approved product.

The Device is a vertebral disc endoprosthesis, as claimed in claims 1, 2 and 6. The following demonstrates the manner in which those claims read on the approved product.

Claim 1 reads on the approved product as follows. The Device is a vertebral disc endoprosthesis comprising relatively rigid superior and inferior concaval-convex elements, each element having an outer surface of predetermined convexity and unreticulated surface roughness for engaging adjacent bone structure which has been milled to mate with said outer convex surface for encouraging bone ingrowth into the mating outer convex surface. Each concaval-convex element of the Device has a continuous, smooth non-porous inner concave surface extending substantially across the entire concaval-convex element, and disposed to confront the opposed concaval-convex element smooth concave surface. The Device also comprises a solid but relatively resilient convex nuclear body located between the confronting concave surfaces of the adjacent concaval-convex elements, the nuclear body engaging but being separate from the adjacent concave surfaces to permit sliding arcuate movement of the concave surfaces over the resilient nuclear body.

Claim 2 reads on the approved product as follows. Each concaval-convex element of the Device is of relatively constant cross-sectional thickness.

Claim 6 reads on the approved product as follows. The resilient convex nuclear body of the Device is shaped and sized, relative to the concave surfaces of the concaval-convex elements, so as to be inhibited from expulsion from the endoprosthesis.

(9) The relevant dates and information pertinent to 35 U.S.C. § 156(g) and 37 C.F.R. 1.740(a)(10)(v), which are being provided in order to enable the Secretary of Health and Human Services to determine the applicable "regulatory review period," are as follows.

Effective date of Investigational Device Exemption ("IDE") #G000123	December 20, 2001
First clinical implant under IDE #G000123	May 28, 2002
Application for product approval initially submitted under Premarket Approval ("PMA") #P060023	June 28, 2006
PMA #P060023 approved	May 12, 2009

(10) A brief description of the activities undertaken during the applicable "regulatory period" with respect to the approved product, and the significant dates applicable to such activities, are as follows.

Filed application for IDE	May 4, 2000
FDA conditionally approved application for IDE #G000123	December 20, 2001
First surgery in IDE study	May 28, 2002
FDA unconditionally approved application for IDE #G000123	June 18, 2003
Last surgery in IDE study	October 8, 2004
Mechanical testing PMA module (first of 5 modules) submitted to FDA	June 15, 2005
Biocompatibility, sterilization, and packaging PMA module (second of 5 modules) submitted to FDA	September 15, 2005
Manufacturing and design control PMA module (third of 5 modules) submitted to FDA	September 15, 2005
Deficiency letter received from FDA on Module 3	October 26, 2005
Deficiency letter received from FDA on Module 2	December 22, 2005
Animal testing (fourth of 5 modules) submitted to FDA	February 28, 2006
Response to FDA deficiency letter for Module 2 submitted	June 23, 2006
Response to FDA deficiency letter for Module 3 submitted	June 23, 2006
Clinical data (fifth of 5 modules) submitted to FDA	June 28, 2006
Amendment to PMA application submitted to FDA	August 28, 2006
Amendment to PMA application submitted to FDA	October 30, 2006

Deficiency letter received from FDA for Modules 1,2, and 4	November 2, 2006
Amendment to PMA application submitted to FDA	January 4, 2007
Response to 11/2/06 deficiencies submitted to FDA	February 19, 2007
Amendment to PMA application submitted to FDA	March 27, 2007
Amendment to PMA application submitted to FDA	June 5, 2007
Meeting of FDA/CDRH review panel, resulting in recommendation for approval	July 17, 2007
Amendment to PMA application submitted to FDA	July 19, 2007
Deficiency letter received from FDA on Module 3	August 2, 2006
Amendment to PMA application submitted to FDA	August 8, 2007
Amendment to PMA application submitted to FDA	August 17, 2007
Response to 8/2/06 deficiencies submitted to FDA	October 25, 2007
Amendment to PMA application submitted to FDA	November 20, 2007
Amendment to PMA application submitted to FDA	November 26, 2007
Amendment to PMA application submitted to FDA	January 3, 2008
Amendment to PMA application submitted to FDA	April 25, 2008
"Approvable" letter issued by FDA	July 31, 2008
Amendment to PMA application submitted to FDA	August 14, 2008
FDA inspection of MSD operations facility for the Device	December 10-31, 2008
FDA issues approval letter	May 12, 2009

(11) In the opinion of MSD, U.S. Patent No. 6,156,067 is eligible for an extension of its term as herein requested, and a statement as to the length of the term extension requested, including how the length of the extension was determined, is as follows.

An extension of the term of U.S. Patent 6,156,067 of 1826 days from November 14, 2014 to and including November 15, 2019 is being requested.

As noted in paragraph 5 above, the current expiration date of U.S. Patent 6,156,067 is November 14, 2014.

Pursuant to 35 U.S.C. § 156(c), the term of a patent eligible for extension under 35 U.S.C. § 156(a) shall be extended by the time equal to the "regulatory review period" (as defined in 35 U.S.C. § 156(g)) for the approved product that occurred after the patent issued. 35 U.S.C. § 156(c) sets forth four exceptions: (1) the eligible period is reduced by and any period during which the applicant did not set with due diligence (there is no such period believed to be pertinent herein); (2) after deduction, if any, under (1), the remaining period calculated under 35 U.S.C. § 156(g)(3)(B)(i) (for approved products that are medical devices) is reduced by one-half; (3) the sum total of the remaining original term of the patent after the product approval and the "regulatory review period" (as defined in 35 U.S.C. § 156(g)) may not exceed fourteen years; and (4) only one patent may be extended for a given regulatory review period.

The applicable "regulatory review period" herein is calculated under 35 U.S.C. §156(g)(3)(A) and (B), by taking one-half of the period calculated under 35 U.S.C. §156(g)(3)(B)(i), as follows (see paragraphs 9 and 10 above).

Effective date of Investigational Device Exemption (IDE) #G000123	December 20, 2001
First clinical implant under IDE #G000123	May 28, 2002
Intervening period (i) [156(g)(3)(B)(i)]	1,491 days
One-half of intervening period (i)	745 days
Application for product approval initially submitted under PMA #P060023	June 28, 2006
PMA #P060023 approved	May 12, 2009
Intervening period (ii) [156(g)(3)(B)(ii)]	1,081

The maximum "regulatory review period" to which MSD is entitled under § 156(c) is believed to be the sum of one-half of the intervening period (i) plus the full intervening period (ii), or 745 days + 1,081 days = 1,826 days. The full amount of this extension does not extend past the date fourteen (14) years from the date of approval (i.e., May 12, 2023), and therefore MSD believes it is entitled to an extension of the term of U.S. Patent No. 6,156,067, to and including November 15, 2019 (i.e., November 14, 2014 + 1,826 days).

(12) MSD acknowledges its duty to disclose to the United States Patent and Trademark Office and the secretary and Health and Human Services any information that is material to the determination of the entitlement sought in the instant application for extension of patent term.

(13) The prescribed fee of $ 1,120 under 37 C.F.R. § 1.20(j)(1) for receiving and acting upon the instant application for extension of patent term is enclosed herewith. Please charge any underpayment or additional fee that may be due to Deposit Account 132546.

(14) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed is as follows: William R. Richter / Registration No. 43,879, Medtronic Spinal and Biologics, 2600 Sofamor Danek Drive, Memphis, Tennessee 38132, (901) 399-2907. William R. Richter also is the signatory on this document, is Senior Patent Counsel for Medtronic and is authorized to act on behalf of Medtronic Spinal and Biologics.

Respectfully submitted,

William R. Richter
Registration No. 43,879

Dated: 7/1/09

Certificate of Service

I hereby certify that this correspondence is being deposited with the U.S. Patent and Trademark Office via EFS-Web on July 1, 2009.

Toni Greer

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